JUL - 5 2000

VORTRAN Medical Technology 1, Inc.

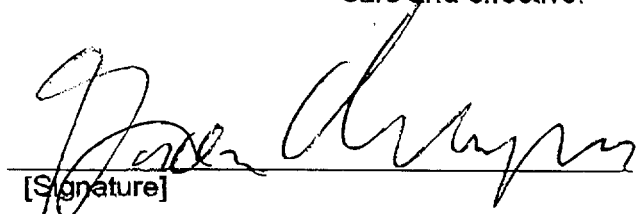
K001430

510(k) Summary

Submitter Information	VORTRAN Medical Technology, Inc. 3941 J Street, Suite 354, Sacramento, CA 95819
Contact Information	James Lee, Senior Vice President TEL: (800) 434-4034 FAX: (916) 454-0490
Trade Name	RespirTech PRO-O_2C™ Model 2200
Common Name	Ventilator, Emergency, Powered (Resuscitator)
Device Class	Class II
Product code	73 BTL
Product classification	per CFR section 868.5925
Classification panel	Anesthesiology
Predicate device	RespirTech PRO™ Model 2000 510(k) No: K973975 VORTRAN Medical Technology, Inc., Sacramento, CA, USA
Device Description	The RespirTech PRO-O_2C™ provides constant flow pressure cycled ventilatory support. The primary working mechanism of the RespirTech PRO-O_2C™ is the Modulator which is an exhalation valve that opens at a set PIP (Peak Inspiratory Pressure) pressure and closes at another lower PEEP (Positive End Expiratory Pressure) pressure. The PMT Modulator provides the actual ventilatory support. During inhalation, exhalation will not start until peak pressure is reached. During exhalation, inhalation will not begin until pressure drops to PEEP. The rest of the RespirTech PRO-O_2C™ consists of the Patient Connector Tee used to supply flow of gas, entrain additional air, and provide a redundant pop-off valve
Intended Use	The device is to be used by properly trained personnel to deliver emergency, short term, constant flow - pressure cycled ventilatory support.
Substantial Equivalency Evaluation	In Vitro Testing per ASTM Designation: F 920 – 93 "Standard Specification for Minimum Performance and Safety requirements for Resuscitators Intended for Use with Humans", and "FDA DRAFT EMERGENCY RESUSCITATOR GUIDANCE" 14 April 1993 868.5925 Powered Emergency Ventilator (Resuscitator) BTL.

510(k) Summary

Operational Characteristics	The RespirTech PRO-O_2C™ runs on a continuous flow of gas (inspiratory flow) of up to 40 L/min. When connected to a 50 PSIG high flow source, the RespirTech PRO will automatically deliver 40 L/min (667 mL/second) of oxygen greater than 85% FiO_2 when supplied with 100% FiO_2 or deliver FiO_2 50% when supplied with 100% oxygen by entraining room air. Peak pressure may be adjusted from between 20 and 50 cm H_2O and PEEP is typically $1/10^{th}$ of PIP. Inspiratory time and rate are adjustable over a wide range. The RespirTech PRO-O_2C™ is equipped with an air entrainment valve which allows the patient to entrain additional air and respond to the demands of the patient (Pressure support). The RespirTech PRO-O_2C™ is also equipped with a redundant pop-off valve that relieves pressure at 60 cm H_2O.
Clinical Application	The RespirTech PRO-O_2C™ provides short term, pressure cycled, constant flow ventilatory support using either pressure control or pressure support. In the pressure support mode the rate dial of the RespirTech PRO is set so that the baseline pressure is above the set PEEP allowing the patient to initiate inhalation by drawing the baseline pressure down to the set PEEP. The RespirTech PRO-O_2C™ is not an ICU stand alone ventilator with multiple monitoring features. Set up and use of the RespirTech PRO-O_2C™ is simple. Set desired flow, adjust pressure dial to obtain desired I-time or tidal volume (see tidal volume chart in instructions), adjust rate dial to obtain desired rate.
Clinical Tests	None
Adverse S & E Information	None
Conclusion	The RespirTech PRO-O_2C™ is substantially equivalent to a predicate device: the RespirTech PRO Model 2000, 510(k) No: K973975. The RespirTech PRO-O_2C™ meets the FDA Draft "Emergency Resuscitator Guidance" and the "Standard Specification for Minimum Performance and Safety requirements for Resuscitators Intended for Use with Humans" ASTM Designation: F 920 – 93 and has been shown to be safe and effective.



[Signature]

June 19, 2000

[Dated]

Gordon A. Wong, M.D.

[Typed Name]

President

[Title]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 5 2000

Gordon A. Wong, M.D.
Vortran Medical Technology 1, Inc.
3941 J Street, Suite 354
Sacramento, CA 95819-3633

Re: K001430
RespirTech PRO-O_2C™ - Model 2200
Regulatory Class: II (two)
Product Code: 73 BTL
Dated: April 17, 2000
Received: April 20, 2000

Dear Dr. Wong:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): **K001430**

Device Name: **Respirtech PRO-O_2C ™**

Indication for Use:

The device is to be used by properly trained personnel to deliver emergency, short term, constant flow - pressure cycled ventilatory support.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use : ✓ OR Over-the-Counter Use _____
(Per 21 CFR 810.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

(Optional Format 1-2-96)